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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,801	08/25/2003	Douglas A. Schein	115621	1325

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OLIFF & BERRIDGE, PLC
P.O. BOX 19928
ALEXANDRIA, VA 22320

EXAMINER

YABUT, DIANE D

ART UNIT	PAPER NUMBER
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3734

MAIL DATE	DELIVERY MODE
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10/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/646,801

Applicant(s)

SCHEIN ET AL.

Examiner

Diane Yabut

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-103 is/are pending in the application.
- 4a) Of the above claim(s) 24-35, 43 and 45-103 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23, 36-42 and 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/26/04; 6/3/04; 9/29/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (Claims 1-44) and Species 4 (Figures 18-23) in the reply filed on 15 June 2007 is acknowledged. The traversal is on the ground(s) that the search and examination of the species would not be a serious burden on the examiner, and therefore the examiner must examine it on the merits. This is not found persuasive because the examiner asserts that the search and examination would be a serious burden considering each invention is distinct, and the combination as claimed does not require a cannula with a groove or ridge and the subcombination can be mounted by a threaded engagement. Also, in the requirement dated 16 April 2007 each of the categories represent a generic disclosed invention having more than one patentably distinct species, which do not overlap in scope are and are not obvious variants of each other. Therefore these alternative inventions and structures would require more than a single search in view of different classification and would impose a serious burden on the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 43 (drawn to Species 3) and 45-103 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention/species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 15 June 2007.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 26 May 2004, 03 June 2004, and 29 September 2005 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-2 and 9-16 are rejected under 35 U.S.C. 102(b) as being anticipated by **Golyakhovsky** (U.S. Patent No. **4,800,879**).

Claims 1-2: Golyakhovsky discloses first **1** and second **2** portions that form a chamber when brought together, a first fitting **11** on one of the top and bottom portions, being in fluid communication with the chamber and having fluid flow substantially perpendicular to fluid flow through the hole, wherein the second portion has a hole ("cavity") **9** in fluid communication with the chamber and adapted to receive a section of tissue at least one sealing surface adapted to secure the section of tissue when the first and second portions are brought together (Figures 1-3).

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Claims 9-16: Golyakhovsky discloses at least one fixing member **14b** and at least one compression strap **14b** arranged to wrap around at least part of the first portion and at least part of the second portion and to engage the fixing member so that the first and second portions are brought together, the compression strap extending from a sealing ring (the top part of first portion **1** that contacts tissue) and at least one engagement member or pre-positioning structure on one of the first and second portions and a complementary engagement member or complementary pre-positioning structure at a free end of the compression strap wherein the engagement member is arranged to engage the complementary engagement member (joined at **3**) while permitting relative movement of the first and second portions such that the first portion is substantially parallel to a second sealing surface on the second portions, also while the compression strap is wrapped around at least a part of the first portion and the second portion and engages the fixing member so that the first and second portions are brought together (Figures 1-3).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over

Golyakhovsky (U.S. Patent No. **4,800,879**).

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Claim 3: Golyakhovsky does not expressly disclose that at least one of the first and second portions being formed of one of a transparent and a translucent material, although Golyakhovsky discloses using plastic, and it would have been obvious to one of ordinary skill in the art at the time of invention to provide a transparent or translucent material increase visibility to ensure proper fluid flow.

8. Claims 4-8, 36-40, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Golyakhovsky** (U.S. Patent No. **4,800,879**) in view of **Robinson** (U.S. Patent No. **6,726,651**).

Claims 4-8, 36-40, and 42: Golyakhovsky discloses the claimed device (see paragraphs 4 and 6) but does not expressly disclose having the chamber being designed to collect gas separate from a fluid flow through the first fitting, the chamber and the hole, or having a second fitting formed on one of the first and second portions and being in fluid communication with the chamber that is formed when the first and second portions are brought together, the fluid flow being substantially perpendicular through the second fitting to the fluid flow through the hole, and the second fitting comprising at least one of a vent and a valve, the second fitting being connectable to a first fitting.

Robinson teaches a chamber **1220** designed to collect gas separate from a fluid flow through the first fitting, the chamber and the hole, or having a second fitting formed on one of the first and second portions and being in fluid communication with the

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chamber that is formed when the first and second portions are brought together, the fluid flow being substantially perpendicular through the second fitting to the fluid flow through the hole, and the second fitting comprising at least one of a vent and a valve **1240**, the second fitting being connectable to a first fitting (Figure 23). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a second fitting, as taught by Robinson, to Golyakhovsky in order to apply several instruments to the cannula while creating a fluid-tight seal.

9. Claims 17 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Golyakhovsky** (U.S. Patent No. **4,800,879**) in view of **Frampton** (U.S. Patent No. **3,538,915**).

Claims 17 and 41: Golyakhovsky discloses the claimed device (see paragraph 4) but does not expressly disclose a flange extending from an outer surface of the second portion.

Frampton teaches a flange **42** extending from an outer surface of the second portion (Figure 1). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a flange extending from the second portion outer surface, as taught by Frampton, to Golyakhovsky in order to increase surface area for contact with the organ and to maintain a sealed engagement.

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10. Claims 18-23 and 44 rejected under 35 U.S.C. 103(a) as being unpatentable over **Golyakhovsky** (U.S. Patent No. **4,800,879**) in view of **Valley** (U.S. Patent No. **5,814,016**).

Claims 18-23, and 44: Golyakhovsky discloses the claimed device (see paragraph 4) but does not expressly disclose a sealing ring disposed between the top and bottom portions made of an elastomeric material, the ring having a complementary shape to the sealing surfaces.

Valley teaches a sealing ring **883** disposed between the top and bottom portions made of an elastomeric material, the ring having a complementary shape to the sealing surfaces (Figure 33, col. 45, lines 50-56). It would have been obvious to one of ordinary skill in the art at the time of invention to provide , as taught by Valley, to Golyakhovsky since it was well known in the art to provide an elastomeric sealing ring or gasket member in between two engaging members to avoid leaks.

Although the sealing surfaces do not have ribs, ridges, cuts, and protrusions, it would have been obvious to one of ordinary skill in the art to provide characteristics to increase the surface area of the ring to create a fluid-tight seal and avoid undesirable leaks.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY

A handwritten signature in black ink, appearing to read "MJ Hayes", with a long horizontal flourish extending to the right.

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER